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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,833	02/06/2004	Brian Jones	2093/15385US01	7170

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1744

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/773,833

Applicant(s)

JONES, BRIAN

Examiner

Nathan A. Bowers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the amplification chamber" in lines 6 and 7. There is insufficient antecedent basis for this limitation in the claim. It is believed that the phrase should be changed to read "the one or more reaction chambers."

Claim 7 recites the limitation "the second channel" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is believed that claim 7 should be dependent on claim 6.

Claim 41 recites the limitation "the amplification chamber" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

- 1) Claims 1, 5-15, 22, 31-38 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson (US 20050250199).

With respect to claims 1 and 22, Anderson discloses a cassette suitable for DNA analysis comprising a top plate (Figure 2:102) and an opposing bottom plate (Figure 2:124) affixed thereto. A plurality of chambers (Figure 2:104) are formed between the plates. This is described in paragraphs [0038]-[0041] and [0121]-[0125]. Paragraphs [0118] and [0119] indicate that the plates are constructed from plastic and are injection molded. Anderson teaches in paragraphs [0130]-[0138] that an isolation chamber (Figure 3:202), reaction chambers (Figure 3:206, 210), a digestion chamber (Figure 3:214), and a separation chamber (Figure 3:218) are provided within the cassette and are in fluid communication with each other. Paragraphs [0009], [0015] and [0123] state that ports are connected to each of the chambers for supply reagents.

With respect to claim 5, Anderson discloses the apparatus disclosed in claim 1 wherein the isolation chamber is associated with a piston suitable for drawing fluid into the chamber. In paragraph [0155], Anderson teaches that a syringe is employed to push a sample through the device.

With respect to claim 6, Anderson discloses the apparatus in claim 1 wherein the isolation chamber is in fluid communication with the one or more reaction chambers by a second channel. Connecting channels (204 and 208) are apparent in Figure 3.

With respect to claim 7, Anderson discloses the apparatus in claim 1 wherein each of the chambers are in communication with channels that have valves operatively

positioned therein. Paragraph [0125] indicates that valves are used to introduce and remove fluids to and from the various chambers.

With respect to claim 8, Anderson discloses the apparatus in claim 1 wherein the reaction chamber suitable for amplifying DNA and the digestion chamber suitable for digesting DNA are the same chamber. Although Anderson teaches in paragraphs [0130]-[0138] that each chamber carries out a specialized function, each of the chambers is *suitable* for accomplishing a plurality of tasks individually. Any of the reaction chambers described by Anderson is fully capable of accomplishing both amplification and digestion.

With respect to claims 9 and 10, Anderson discloses the apparatus in claim 1 wherein the reaction chamber is in fluid communication with the separation chamber by a third channel (Figure 3:216). Anderson teaches that fluids move from the reaction chambers, through the digestion chamber, and to the separation chamber via a system of channels. As previously described, the channels leading to each chamber each have a valve operatively positioned therein.

With respect to claims 11-15, Anderson discloses the apparatus in claim 1 wherein the separation chamber has a separation medium therein. Paragraphs [0138]-[0140] teach that the separation medium is an electrophoretic medium positioned within a capillary. The separation chamber comprises a transparent window for observation or scanning of the particular analysis being performed. Although not expressly stated, it is clearly implied that window is sufficiently transparent to visible light.

With respect to claims 31 and 32, Anderson discloses the apparatus in claims 7 and 10 wherein the valves comprise an elastomeric rubber. In paragraph [0125], Anderson states that valves (Figure 2:114) are formed using any flexible polymer, such as latex rubber. Paragraph [0125] additionally states that the valves are actuated through the application of a pressure or vacuum.

With respect to claims 33-38, Anderson discloses the apparatus in claim 6 wherein the isolation chamber is connected to 1 reaction chamber that is also fully capable of doubling as a digestion chamber. The 1 reaction/digestion chamber is in communication with 1 or multiple (Figure 3:226) application points on an electrophoretic gel positioned within the separation chamber. Gel matrices are described in paragraph [0100].

With respect to claim 41, Anderson discloses a cassette suitable for DNA analysis comprising a top plate (Figure 2:102) and an opposing bottom plate (Figure 2:124) affixed thereto. A plurality of chambers (Figure 2:104) are formed between the plates. This is described in paragraphs [0038]-[0041] and [0121]-[0125]. Paragraphs [0118] and [0119] indicate that the plates are constructed from plastic and are injection molded. Anderson teaches in paragraphs [0130]-[0138] that an isolation chamber (Figure 3:202), reaction chambers (Figure 3:206, 210), a digestion chamber (Figure 3:214), and a separation chamber (Figure 3:218) are provided within the cassette and are in fluid communication with each other. Paragraphs [0009], [0015] and [0123] state that ports are connected to each of the chambers for supply reagents. Anderson additionally teaches that each of the chambers are in communication with channels that

have valves operatively positioned therein. Paragraph [0125] indicates that valves are used to introduce and remove fluids to and from the various chambers via ports.

2) Claims 1-13, 23-27, 30-36 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Mathies (US 20040209354).

With respect to claims 1, 8 and 41, Mathies discloses a cassette suitable for DNA analysis comprising a top plate (Figure 1:101) affixed to an opposing bottom plate (Figure 1:105). Paragraph [0028] and claim 2 of Mathies indicate that the plates are constructed from plastic and are capable of forming a plurality of chambers. Mathies discloses an isolation chamber (Figure 12:1211) in communication with a reaction chamber (Figure 12:1201) useful for accomplishing digestion and amplification. This digestion/amplification chamber is in fluidly connected to an additional purification reaction chamber (Figure 11:1101) and a detection chamber (Figure 11:1113) in the form of a capillary electrophoresis microchannel. This described in paragraphs [0067], [0068] and [0089]-[0091]. Each chamber is in communication with a channel that comprises an inlet and a valve. Valve construction is discussed in paragraphs [0036]-[0041].

With respect to claims 2-4, Mathies discloses the apparatus in claim 1 wherein a waste chamber (Figure 12:1213) is provided for collecting undesirable compounds. The waste chamber is in communication with the isolation chamber via a system of channels and valves (Figure 12:1221, 1223). This is described in paragraph [0091].

With respect to claims 6, 7, 9 and 10, Mathies discloses the apparatus in claim 1 wherein the isolation chamber, reaction chambers, and detection chamber are all fluidly connected via a plurality of channels and associated valves. This is apparent from the Figures.

With respect to claims 11-13, Mathies discloses the apparatus in claim 1 wherein the separation chamber comprises an electrophoretic medium positioned within a capillary. This is described in paragraph [0068].

With respect to claims 23-27 and 30-32, Mathies discloses the apparatus in claims 4, 7 and 10 wherein the valves comprise an elastomeric polymer material (Figure 1:111). In paragraph [0036], Mathies states that are formed using any flexible membrane. Elastomeric rubber membranes are considered to be well known in the art. Paragraph [0037] additionally states that the valves are actuated through the application of a pressure or vacuum.

With respect to claims 33-36, Mathies discloses the apparatus in claim 6 wherein the isolation chamber is connected to 1 reaction chamber that is also fully capable of doubling as a digestion chamber. The 1 reaction/digestion chamber is in communication with 1 or multiple application points on an electrophoretic capillary positioned within the separation chamber.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3) Claims 2-4 and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US 20050250199) as applied to claim 1, and further in view of Pourahmadi (US 20020055167).

With respect to claims 2-4, 23-27 and 30, Anderson discloses the apparatus as set forth in the 35 U.S.C. 102 rejections above, however does not expressly disclose the use of a waste chamber.

Pourahmadi discloses a cassette suitable for DNA analysis comprising a top plate and a bottom plate that are combined to form a plurality of chambers therebetween. In paragraph [0199], Pourahmadi teaches that a waste chamber (Figure 16:203) is in fluid communication with an isolation chamber (Figure 16:177).

Anderson and Pourahmadi are analogous art because they are from the same field of endeavor regarding microfluidic analytical devices.

At the time of the invention, it would have been obvious to connect a waste chamber to the isolation chamber disclosed by Anderson. The use of waste chambers is considered to be well known in the microfluidic processing art, and the inclusion of a waste chamber would have required only minor alterations to the device of Anderson. Waste chambers are beneficial because they allow one to divert buffers, contaminants, and other wastes away from streams carrying the analytes of interest.

With respect to claims 28 and 29, Anderson and Pourahmadi disclose the apparatus set forth in claim 27 as set forth in the 35 U.S.C. 103 rejection above. In addition, Anderson teaches in paragraph [0116] that the upper plate is affixed to the lower plate using an adhesive.

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4) Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson (US 20050250199) as applied to claim 14, and further in view of Bass (US 20030203368).

With respect to claims 16-19, Anderson discloses the apparatus set forth in claim 14 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly state that the separation chamber is transparent to UV light.

Bass discloses a DNA detection device that includes a plurality of arrays capable of selectively binding to a biopolymer analyte. Bass teaches in paragraph [0039] that detection is facilitated through the use of a detection area that is transparent to visible and UV light.

Anderson and Bass are analogous art because they are from the same field of endeavor regarding optical detection devices.

At the time of the invention, it would have been obvious to ensure that the detection window disclosed by Anderson is transparent to UV light. As indicated by Bass, optical detection systems often utilize excitation and emission light characterized by wavelengths in the UV range. The exact degree to which the window is transmissible to UV light is considered to be result effective variable that is optimized through routine experimentation. At the time of the invention, it would have been obvious to ensure that the separation chamber of Anderson was 90% to 97% transmissible to UV light if it was determined that these values produced the best results. See MPEP 2144.05.

With respect to claims 20 and 21, Anderson and Bass disclose the apparatus set forth in claim 19 as set forth in the 35 U.S.C. 103 rejection above. In addition, Anderson discloses in paragraph [0119] the use of acrylic plastics in the formation of the top and bottom plates. Polymethylmethacrylate is considered to be a well known acrylic plastic.

5) Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Anderson (US 20050250199) or Mathies (US 20040209354) each as applied to claim 1, and further in view of Bardell (US 20020015959).

Anderson and Mathies disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejections above, however do not expressly indicate the use of a mixing chamber in contact with the separation chamber.

Bardell discloses a system for mixing biological analytes in a separation chamber. Paragraph [0029] teaches that syringe pumps (Figure 6:54, 56) are used drawing and pushing fluids across a reaction area.

Anderson, Mathies and Bardell are analogous art because they are from the same field of endeavor regarding microfluidic detection devices.

At the time of the invention, it would have been obvious to provide the devices of Anderson and Mathies with a mixing chamber capable of thoroughly agitating a reaction solution. In paragraph [0010], Bardell indicates that mixing chambers are beneficial because they increase the overall process time of analysis, while providing for more accurate results. As evidenced by Bardell, the use of pistons and plungers to influence fluid movement is known in the art.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Handique (US 20060205085), Tanaami (US 20040137607), Zanzucchi (US 5858804) and Schnipelsky (US 6645758) references disclose the state of the art regarding cassettes suitable for DNA analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

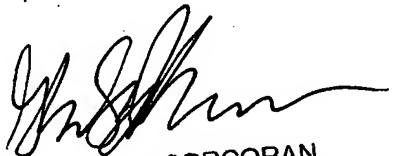
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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